

**FDA Townhall with NIH and VA: 3D Printed Swabs**

**Moderator: Irene Aihie  
May 15, 2020  
1:00 pm T**

Coordinator: Welcome and thank you for standing by.

At this time all participants are in a listen-only mode until the question-and-answer session of today's conference. At that time you may press star 1 on your phone to ask a question.

I would like to inform all parties that today's conference is being recorded. If you have any objections you may disconnect at this time.

I would now like to turn the conference over to Irene Aihie. Thank you. You may begin.

Irene Aihie: Hello. Welcome to today's FDA town hall. I am Irene Aihie of CDRH's Office of Communication and Education.

Today we will discuss the production and use of 3D printed swabs during the COVID-19 public health emergency. This is a collaboration between the FDA, the Department of Veterans Affairs (VA) Innovation Ecosystem and the National Institutes of Health (NIH) 3D Print Exchange.

The FDA's policy for diagnostic tests for coronavirus disease 2019 during the public health emergency was issued on February 29, 2020 to help accelerate the availability of novel coronavirus tests developed by laboratories and commercial manufacturers for the duration of the public health emergency. This guidance was updated on March 16, May 4 and May 11, 2020.

Today Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health in the Office of Product Evaluation and Quality, here in CDRH at FDA, will open this discussion on 3D printed swabs during the COVID-19 public health emergency. He is joined by other members of CDRH, FDA as well as NIH and VA.

Following the presentation, we will open the line for your questions related to information provided during the presentation.

Now, I give you Tim.

Timothy Stenzel: Welcome and thank you joining us today for this 3D printed swab virtual town hall. This represents a collaboration between the FDA, the VA and the NIH. We are keenly aware of spot shortages of a number of supplies and reagents and are looking at maximum regulatory flexibility of these stated needs during these unprecedented times during this pandemic.

We welcome input in collaboration with all to help address these needs. This virtual town hall is just such an example of outreach and collaboration and interaction. And we have an amazing group of subject matter experts on the call today.

We look forward to a very productive meeting and a very interactive meeting.

And with that, I turn it over to Dr. Sara Brenner.

Dr. Brenner: Thank you, Tim. This is Sara. And I thank everyone for being on the call today. Many folks I'm sure who have dialed in have been engaged with dialogue with Tim and I through the OIR town halls, which have been happening for many weeks and where you have heard mention of 3D printed swabs.

I am joined today by other colleagues across FDA including members of our team in the Office of In Vitro Diagnostics. We also have the Office of Strategic Partnership and Technology Innovation, the Office of Chief Scientist, the Office of Science and Engineering Laboratories as well as our fantastic colleagues from the National Institute of Allergy and Infectious Diseases at NIH and the Veterans Health Administration Ecosystem.

So the goals of this town hall today, and then we'll get into this, are generally to provide an engagement and dialogue opportunity with the community. We're aware, as Tim mentioned, that there are many folks who are looking for ways to engage and to help address shortages particularly through an innovative means of making swabs.

We'd like to also discuss the great work being done under our collaborative Memorandum of Understanding with our federal partners at NIH and FDA which focuses on 3D and additive manufacturing broadly.

We'll also discuss considerations that experts in these agencies as well as the community believe are important for swab use in COVID-19 testing. We would very much like to recognize the important work being done by everyone who has dialed in and all of the folks who have reached out to us and asked questions that you were seeking answers to.

To wrap-up the call, we will have a brief Q&A, and then we would like to point stakeholders toward a path forward for further engagement.

So with that, I'm going to turn it over to Matthew Di Prima at the FDA in the Office of Science and Engineering Laboratories who will provide some insight on the federal partnership under our MOU.

Dr. Di Prima: Thank you so much, Sara.

As Sara mentioned, I am going to briefly discuss the Memorandum of Understanding titled Rapid Response to COVID-19 Using 3D Printing which is between the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Veterans Administration (VA).

So for a complete background, in late March there was a significant groundswell of support from the additive manufacturing and 3D printing communities to address COVID-related shortages and the community was really looking for help in understanding how they could engage with health partners and address the supply shortage.

And so to support the community, the VA, NIH and FDA entered into this Memorandum of Understanding (MOU) to create a way for legally marketed products to be presented to the community and then to ultimately connect manufacturers with those with clinical needs.

So the very first goal of the MOU was in fact to connect health care organizations with shortage needs to manufacturers who have the capacity to address those needs. We are hoping to be able to share 3D printing files as well as lessons learned with the community to make sure that these products

can be made as widely and as effectively as possible.

We are working to do consultation on models, testing and practices and then engage with the community to make sure that the products being printed meet the clinical needs.

We wanted to provide a bridge for discussion regarding clinical and community safety for products that aren't typically approved by the FDA. So these were for legally marketed products that don't meet FDA pre-market approval but community and clinical locations still wanted some level of understanding of how these products would perform.

One is to provide a shortened list of these 3D printable products so, again, manufacturers and clinicians could understand what was available to the community to address their specific needs, or for the manufacturing side, what products they could manufacture.

And we're also very interested in outreach and education to both the manufacturing and the health care community about alternative ways to address medical products during the pandemic as well as to engage with manufacturers who weren't traditionally used to manufacturing medical products.

So for each agency there are a series of specific roles. The FDA under the MOU provides engineering and support in evaluating and developing tests for 3D printed products or providing insight into regulatory the framework and requirements for the range of products being looked at under an MOU as well as to support community engagement and outreach to ensure health care workers and patients have access to key medical products during the COVID pandemic.

NIH, through their 3D Print Exchange, agreed to host the repository of products to be printed during the COVID response. They cataloged and organized files so users can easily access the data they need to determine the appropriateness of their situation.

And they've been actively developing communication and print resources for the print exchange community to explain the different regulatory requirements around some of these products as well as best practices to make them.

The Veterans Health Administration has been providing key clinical and engineering expertise in the evaluation process. Significantly they've been doing a lot of clinical evaluation of these designs to make sure that face masks and face shields and other products will work in a clinical environment.

They've been also coordinating with other groups for clinical testing as well as some of the materials testing that they perform and they've been key in providing communication and feedback back to the designers about potential improvement to the process.

Now not mentioned in the Memorandum of Understanding but a key partner with us has been America Makes, which is a public-private partnership of which the FDA is a member. And we've been working with America Makes to partner with industry as well as working to connect industry with the clinical needs going back to our very first bullet point for the MOU.

They've also been key in coordinating with other government and industry bodies as we've been working to engage in greater manufacturing communities as well as a broad number of government entities with 3D printing capabilities.

And they've also been hosting outreach and educational events to increase the impact of the work. So some key specifics on how this effort has performed, to date America Makes has matched over 170,000 pieces of equipment, most primarily PPEs between manufacturers and clinical sites. And then they have over 400 manufacturers who have logged into their website and provided information on their manufacturing capabilities.

On the NIH Print Exchange side, we've received almost 460 designs, of which 18 have passed a clinical assessment and 14 other designs have been found appropriate for community use. And so far there have been 34 devices with significant warnings based off of their performance.

In terms of the NIH print exchange, the repository, that COVID-19 page, has been viewed almost 200,000 times since launch. A total collected view of all models has exceeded 1 million views. And the top ten designs have been downloaded over 70,000 times.

Some key thoughts as we're moving forward is it appears that 3D printed swabs are a good candidate for this pathway given the legally marketed classification for them as well as the COVID related shortage needs.

And with that, I would like to introduce Dr. Phillip Cruz of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health.

Dr. Cruz: Thank you, Matthew. So if I could have the next slide, please. Okay. So I'd like to review briefly the history and the role of the NIH 3D Print Exchange with this effort. And it was started in 2013 and it is currently directed by Dr. Meghan McCarthy, who unfortunately was not able to be here today.

And if I could have the next slide, please. This slide just gives a brief background on the place of the 3D Print Exchange within NIH. It's actually managed out of the National Institute of Allergy and Infectious Diseases, which is one of the 27 institutes and centers at NIH. This is the one that is directed by Dr. Anthony Fauci.

And our group is actually part of the IT Department for that institute, the Office of Cyber Infrastructure and Computational Biology where we have a group of developers and scientists. And we do software development project management and research consulting.

And could I have the next slide, please? So back in 2013 there was a recognized need for a place for storing and creating and sharing biomedical 3D models for the purpose of 3D printing. And as a result of that meeting, the NIH 3D Print Exchange was born.

And this is an example of some of the kinds of content that's available on the site, including the first two models shown here, which are part of the current SARS COVID-2 collection of protein and viral structures from experimental data that are on site. And you can see the URL for the home page there at the top.

Next slide, please. So as a result of the MOU and as Matthew just described, there have been a large number of submissions of 3D models for printing to the site. And a couple of examples of things that are available are shown on this slide.

And if I can go to the next slide, please. So the URL at the left shows the collection, the latest of the COVID-19 response on the site. And at the right is



a screen capture of that particular page showing some of the models that have been reviewed for clinical use and then assistance for both our creators, manufacturers and users of the site on how to best use it and how to contribute to it.

And so this is kind of the main landing page related to the supply chain response effort. And as Matthew mentioned earlier, it has had quite a bit of interest as indicated by the stats that you mentioned.

Next slide, please. So I'm not going to go into the specifics for the site use any further except to mention the one about two-thirds of the way down. We've had a 1,390% increase in visitors compared to the previous period. So this has made a huge impact on our size and hopefully we're making an impact on the COVID-19 response as well.

Next slide, please. So if you do go to the site to contribute some data or contribute models, you would go to what we call the share page. And this is an example of what that looks like. Each of those tabs allows you to provide all the information that's necessary to go along with your model and allows you to update the 3D printable files that you can then share on the site.

And then if we go to the next slide, please. So if you go to the top tab, the general information tab, because I'm not going to go through all of them. Just to show you that there's additional field that you can fill out with the metadata associated with your submission.

For instance, for the device used you could use general equipment or adapter. And the more information that you can provide the better it is for looking at and for others to evaluate your submission to the site.

Next slide, please. So the current thinking for swabs and the clinical considerations that are on the slide will be on this page here, [this URL](#). This page is not live yet. It should be live later today and it will be updated continuously as the thinking on swabs continues to evolve. So just keep in mind that this is the place to go for the current information that we will have on the slide.

Next slide, please. I just want to thank all of our partners in this effort. It's been a fantastic team and a fantastic experience for all of us.

And next slide, please. And if you have any questions related to the site itself, send them to [3dprint@nih.gov](mailto:3dprint@nih.gov).

And now I'd like to introduce Dr. Beth Ripley, who is the director of the Veterans Health Administration 3D printing networks at VA Health Care Systems.

Dr. Ripley: Thank you, Phil.

As we've been saying, this partnership has really been about acting fast to help front line staff, concerning COVID-19, have access to the safest and most effective 3D printed personal protective equipment and other medical supplies.

The role that VA is playing in this partnership is really in the clinical testing of the 3D printed design. So the 3D printed network prints the parts. We test the safety and clinical efficacies. This is all done in collaboration with VA front line medical providers and staff.

As the largest health care system with thousands of researchers embedded in

our hospitals and hundreds of innovation specialists, we have both the scientific knowledge and agility and flexibility to anticipate novel solutions and react accordingly.

And I believe we all on this call recognize that unanticipated disruptions in supply chains can leave health care systems vulnerable, so we have a larger general interest in the concept of digital stockpiling of device designs that can be called on during the current or future crises.

So why nasal swabs? It's really important that we determine the effectiveness of nasal, nasopharyngeal or anterior nares swabs to ensure that we have appropriate clinical information to care for our patients as false positive and false negative results could introduce errors in treatment plans and place patients and staff at unnecessary risk.

Further, there's no clear precedent for 3D printed nasal, nasopharyngeal and other swabs. There is some great initial work and studies out there that have looked at the effectiveness. But we felt that there was need for additional data around this topic.

So what role does VA have with respect to swabs? What we're hoping to do is leverage what we've done so far within the MOU, which is come up with clinical protocols that assess the effectiveness of 3D printed products for use in hospitals such as face shields, 3D printed face masks and other accessories.

Really our intent is to consider all of the unique features that go into 3D printed swabs and develop the testing protocol that will demonstrate equivalents to the standard of care. This protocol will be shared publicly under the spirit of the MOU.

I do want to be clear that our intent is not to endorse any specific swab design. Instead we're really looking to create a framework for assessment of all swabs that fit into this unique category. We also recognize that swabs are made with different printing technologies, materials, designs and sterilization processes.

We are endeavoring to provide a protocol that takes these variabilities into consideration. We believe this study protocol could be useful beyond the COVID-19 pandemic as we may face similar scenarios in the future.

We also understand that although 3D printing technologies present certain challenges, most notably the lack of years of scientific data on the trial uses in medicine, we view this as a great opportunity to contribute to the knowledge in the field that will grow this emerging technology in medicine.

When thinking about this protocol, we will be considering certain design characteristics, which will be published on the NIH 3D Print Exchange. And we can talk about those more in the Q&A, but for example, we're thinking about things such as, is the swab size and shape sufficient for passing through the nasal cavity and reaching the intended sampling location?

Is it unobtrusive enough to minimize the risk of epistaxis or discomfort to the patient? Is it able to effectively absorb the sample, the elusive sample and not interfere with the testing assays and more?

So with that I'd like to turn it over to Sara Brenner from the FDA Office of In Vitro Diagnostics.

Dr. Brenner: Thank you, Beth. And I am back. I'm going to just briefly discuss some things for consideration that hopefully provide a bit of a response to the numerous questions, hundreds of emails and other types of outreach, that we are aware

of on this topic.

In terms of technical considerations around the development and evaluation of 3D swabs for clinical use as described by Beth and Phil, our hope is that this collaboration will lead to more clarity in this area as our agencies continue to work together and with experts in the community.

So as we move on from this call, we look forward to discussing various points of view on technical considerations in the spirit of sharing expertise as part of engaging stakeholders who are working diligently to address pertinent needs, including supply shortages during this public health emergency.

So we'd like to briefly outline some of the considerations that may be valuable to provide consistency in developing and validating 3D printed swabs in this case.

To be clear, we are not providing any regulatory determinations or guidance on this call today. Rather, we are introducing these topics for continued discussion amongst our federal colleagues and the larger stakeholder community.

Nasopharyngeal and nasal swabs, also referred to as absorbent tip applicators, are generally provided sterile and individually packed for single use. Sterility packaging and labeling are important considerations for these devices.

As these devices have not traditionally been produced using additive manufacturing, there may be unique considerations for the new 3D printed version. FDA's guidance document on "[Technical Considerations for Additive Manufactured Medical Devices](#)" includes considerations specific to 3D printing, such as materials, controls, post-processing and overall process

validation.

Since swabs are used internally, it is important to consider the biocompatibility of the materials, including any potential effects on the material from the process of sterilization. Material considerations may include a history of safe use, including any prior verification that a material is non-cytotoxic, non-irritating and non-sensitizing.

It's also important to consider the mechanical properties, flexibility and durability of the 3D printed swab after sterilization. While there are currently no testing standards for swabs, there are existing standards for tensile, torsional and flexional testing that could be considered when assessing a swab's mechanical properties.

Since 3D printed swabs may have different functional properties than traditionally manufactured swabs, it is also important to consider the analytical and clinical applicability as has been previously described.

It's important that the swabs be able to adequately collect clinical specimens without damaging tissue and be able to sufficiently collect, retain and elute clinical specimens for downstream analysis.

It's also critical in this case that swabs be compatible with and not negatively affect representative downstream assays such as PCR or antigen tests. We are excited to continue discussions on these topics through this collaborative effort. And with that, I would like to turn it over to James Coburn in the Office of the Chief Scientist at FDA.

James Coburn: Thanks very much. So my role here is to give a little bit of information about the future engagement and next steps for those who want to take them with

how you can engage with us and the other federal agencies involved.

First of all, as you see on the screen, there are websites for the partners here of the MOU, and America Makes also has a website for COVID-19. It is [americamakes.us/COVID19](https://americamakes.us/COVID19), all one word. And those websites provide all of the updated resources on what designs are in the pipeline, what are the properties that people are following, and what the community's best practices are as collected by that MOU community and the invited people who are involved in that community.

If you are looking specifically to engage on things in the nasal swab arena, you can follow that same pipeline that Dr. Cruz outlined for the NIH website and look at existing best practices around design testing for those swabs. There should be a nasal swab link from the general link that he posted.

Soon there will be a collected wisdom document where just the general design considerations, technical wisdom and other things from experts and stakeholders that people have written in and people have talked to that will be on that website, so that you know where your benchmarks are as well as all the standards. So we've listed all those standards there.

And as Dr. Ripley mentioned, there will be an example protocol from the VA that they will be following and they will give for other people to follow as well.

So once you have those items in your package, essentially, you can post that information to the NIH website, the design, the test data, the reports.

Unlike some of the other images and designs that are on there, you do not have to post your 3D design or printable file on there, depending on what you

want to do as long as there is kind of a description of that, maybe a picture of it, and the test data so people on the backend will be able to look at that, evaluate to see if that design is essentially conforming with or compatible to traditional swabs. And then give it that clinically reviewed badge on the website.

If you haven't been to the NIH website, you will see that they are tested. There are prototypes. And then there are clinically reviewed badges. So that will give it a little extra official marker there.

The contact and other information on how someone can use your design should also be included in that. We want people to be able to use it or you want people to be able to get in contact with you so they can connect to you. So post that on the NIH website.

Also consider connecting with the America Makes group if you are a manufacturer. They have a manufacturer button. You say what you can do. What you have the capacity to do. And they can connect you with health care workers who need that resource.

Lastly I would say that additional specific information on the data checklist that NIH and VA and the MOU is going to want to see to make that clinically reviewed badge a possibility is going to be posted soon as well as physician workflow and comparative criteria for the traditional swab.

That way everybody will just have an open playbook. It's really about making things available to the community and opening up the playbook so that we can get things done quickly, efficiently and still safely.

So stay tuned to those websites for updates. You can see them right here. If



you have specific questions, you can, of course, contact the FDA at COVIDmanufacturing@fda.hhs.gov.

The NIH Print Exchange can be contacted at 3Dprint@nih.gov. And you can go to their website and you can also go to the americamakes.us/covid19 website, which has a form. You can contact them as well. With that, I believe the next up is to turn it back to the operator to have question and answer time.

Coordinator: Thank you. We will now begin the question-and-answer session. If you would like to ask a question, please press star 1, unmute your phone and record your name clearly. Your name is required to introduce your question.

If you need to withdraw your question, press star 2. Again to ask a question, please press star 1. It will take a few moments for the questions to come through. Please stand by.

Our first question comes from (Jim Linder). Your line is now open.

(Jim Linder): Thank you very much. The statement was made that one may need to demonstrate equivalents to the current fiber-based swabs. How will you handle the situation if the 3D printed swabs actually collect more cells?

Dr. Brenner: This is Sara from FDA. That's an excellent question. And I guess we would look forward to the possibility that 3D printed swabs might actually out-perform conventional swabs. I can't say specifically how we would handle that.

But I would strongly encourage you to conduct testing and engage with us through the NIH and FDA, as has been described, to collect that data and so that we can all learn together about how the performance compares to the

conventional swab.

(Jim Linder): Thank you.

Coordinator: Our next question comes from (Nicholas). Your line is now open.

(Nicholas): Hi. Yes. This is a bit of a two-parter. I represent a research group at the New Jersey Institute of Technology. We recently posted a design to the NIH form. Mostly I heard the term nasal swabs and rarely pharyngeal. Is it a certainty that we're working away from throat swabs and looking just toward nasal swabs?

Dr. Brenner: This is Sara from FDA. Was the question, are we looking at nasal and nasopharyngeal versus what was the other type of swab you asked about?

(Nicholas): No. Are we looking at just nasal or are we moving away from the possibility of throat?

Dr. Brenner: I'm afraid I missed that last part again. However, from our perspective I don't think we're indicating a movement towards or away from any particular type of swab. That's sort of a different question.

But I would encourage you to investigate and proceed with the research and development of any of the swab alternatives for the collection devices that are being used, which do include nasopharyngeal, pharyngeal and nares swabs.

(Nicholas): That's good to know because my follow-up to that is the design posted is the design for throat only, and I was wondering if there was any way we could follow-up with getting that verified because we've gotten some great research back on sterilization processes, promising stuff, so we were wondering if there

was any way to follow-up and move forward with that.

Dr. Brenner: Okay. I understand now. Yes, that's been a topic that we're exploring, you know, all different types of collection devices. So, yes, I would encourage you to reach out with regards to submitting your designs to NIH. And I believe that we would look forward to receiving any additional data and information from research.

(Nicholas): Is there an email that's best to follow-up with if it's already been submitted?

Dr. Brenner: I believe that was the one that Dr. Phil Cruz put up and was previously mentioned. So could we provide that email again verbally?

Dr. Cruz: Yes. It's 3Dprint@nih.gov.

(Nicholas): All right. Awesome. I do have it down. So I will follow-up right after this call. Thank you very much.

Dr. Brenner: Great. Thanks.

Coordinator: Our next question comes from (Richard Nicholas). Your line is now open.

(Richard Nicholas): Yes. We already have a swab that has already been tested and reviewed at Harvard Medical. We have all of the data supporting it and everything. It's got 180 degrees worth of bend to it. The product itself - the material is already being used medically. It's registered with the FDA.

How do we go about getting that product to the NIH so that way the government knows that product is now available?

Dr. Brenner: Great. Phil, would you like to take that for NIH?

Dr. Cruz: Yes. Just go to the page that I mentioned earlier, the share page on the site. And you will be able to make a submission to the site just by entering all the information there.

(Richard Nicholas): Because we currently have the ability to ramp up to a million swabs a month. And so we're looking at - we're just looking at the proper areas to go through.

James Coburn: This is James Coburn. You may also want to put that capacity on the America Makes manufacturer site so that people that are not just on the government side of things know that you have that capacity available.

(Richard Nicholas): Thank you very much.

Coordinator: Our next question comes from (Mathew White). Your line is now open.

(Mathew White): Hi. So I got pulled away a little bit. But we have a file for a swab that's been tested and approved. But we are only ISO 1345 compliant and not certified. Is there any way to provide you without being officially certified by ISO standards?

Dr. Brenner: This is Sara from FDA. What I would encourage you to do is reach out to perhaps all of us simultaneously, NIH, VA and FDA, with regards to that specific question on ISO standards and what your specific manufacturing capability is and we will try to get you an answer.

(Mathew White): Okay. Could you read off those emails again?

Dr. Brenner: For FDA, COVIDmanufacturing@fda.hhs.gov. The NIH was 3Dprint@nih.gov and I'm not sure, Beth, if you provided an email for VA? If you want to now, you can. Otherwise you can just send to the two of us and we'll loop in VA.

(Mathew White): Okay. Can you...

Dr. Ripley: If you could just loop us in that would be great.

Dr. Brenner: Okay. Will do.

(Mathew White): What was the very end of the last one, covidmanufacturing@fda.

Dr. Brenner: hhs.gov.

(Mathew White): hhs.gov, okay. Perfect. Thank you.

Coordinator: Our next question comes from (Ben Glendell-Ingler). Your line is now open.

(Ben Glendell-Ingler): Hi, everyone. Thank you for the time today and the information. We've kind of been at this for a little while with a number of you who are on the call. A few observations is this approach seems organized with the major community in the open source approach where the NIH and the VA are taking on responsibilities that are typical of the medical device manufacturer.

And for PPEs, the FDA has raised emergency enforcement policies that waive many regulations such as 21 CFR Part A 20 and GMP. This type of guidance documentation has provided a clear benchmark for the risk to benefit of use of product manufactured in compliance with this guidance during the COVID-19 crisis. And I think this continues to not be the case for NP swabs.

Now I think there's a big difference between interest meaning page views and impact and 170,000 pieces of PPE is really great. And I applaud you all for your efforts and that. But the demand is much greater and we've needed swabs for over two months. And we need swabs now.

So at the end of the day, you know, the swab is a Class 1 exempt device. So is what was announced today in your approval pathway an opportunity to collaborate and accelerate work that is done already? And are you going to take action against manufacturers for doing the traditional pathways that are already distributing?

Dr. Brenner: This is Sara from FDA. Thank you so much for sharing those thoughts, observations and comments. And you're right, we are aware of the need and some of the concerns you've just raised. We've been also hearing about this for a while.

So I want to acknowledge that, and I want to thank you for your patience as we're working through how to most appropriately respond and aid the community.

Unfortunately today we are not providing any regulatory determinations or guidance specifically. But I do encourage you to stay tuned. And we are hopeful that we will be able to more directly answer your questions in the very near future.

(Ben Glendell-Ingler): Thank you. And if one of our manufacturers already has VA Hospitals as customers, are they in the system and is the VA already aware of these or do we need to add them to the portals that have been developed?

Dr. Brenner: I would ask Dr. Beth Ripley to address that from VA's perspective.

Dr. Ripley: Yes. So this is Beth. From the VA's perspective we are aware of the need for swabs and the inputs within our hospitals for utilizing swabs. What we want to do as an organization is ensure that those swabs are meeting these same standards as the potential swabs when there is a choice between the two. And that is why we're actively engaged in a protocol to test multiple swabs and provide that data.

So we are highly motivated. We hear you and we are working towards that as a VA enterprise and beyond. As I said, not only are we here for VA and veterans, but as our fourth mission states we want to support the community and that's why the Office of Health will be open and we will be sharing data out through the MOU to make sure that it impacts the greater society.

Dr. Di Prima: And this is Matthew Di Prima from FDA. I want to provide some clarification. The MOU is not an alternative pathway. It's only for products that are legally marketed. Whether that's based off their base regulatory classification or from immediate effective guidance or EUAs. So this is totally optional and does not replace any FDA pre-market approach.

What it does, however, offer is the potential for a 3D printed swab to have a mark of clinical assessment through the MOU to address any concerns about the performance from diagnostic facilities or other hospitals.

(Ben Glendell-Ingler): Thank you.

Coordinator: Our next question comes from (John). Your line is now open.

(John): Hello. I was wondering what sterilization technique is recommended. I saw

hydrogen peroxide plasma technique was working for the swab.

Dr. Brenner: This is Sara from FDA. It was a little muffled. But I believe the question was about sterilization procedures. At this time, we don't have a recommendation on a specific sterilization procedure or anything like that. However, we're aware that sterilization is important. This is an important point of discussion in the community in determining what the best methods might be.

And we would encourage you again, to reach out to NIH, FDA and VA perhaps simultaneously to begin a conversation or jump into existing conversations on the most appropriate potential sterilization techniques as well as how to investigate the swabs once they've been sterilized, in other words, to evaluate what the effect of the sterilization process has been on the swab.

(John): Excellent. Thank you.

Coordinator: Our next question comes from (Mark Paxton). Your line is now open.

(Mark Paxton): Can I get a question in? I'm sorry. I was speaking with my mute on. Are you there?

Dr. Brenner: Yes. We're here.

(Mark Paxton): I'm so sorry. You hit the nail on the button a little bit here. My question is a follow-on question to the gentlemen that just preceded me was really about the standard for sterility assurance. You touched on it a little bit.

But is there a particular standard ISO, USP or any other standard that might be



out there that the agency is evaluating or requires? And I recognize that the device panels for both specimen collection kit bands for the non-sterile swabs are older device panels. So any insight that you have on that would be greatly appreciated. Over.

Dr. Brenner: Great. Thank you. Yes. We don't at this point have anything specific today with regards to a recommendation or what we would desire to see. You know, again, we're aware that there are a lot of different techniques being tried.

There are many different approaches that people have even started to publish on and produce data on. So we would like to be aware and informed as that information as it is coming forth.

And similar to the previous caller, I would encourage you to jump into that conversation that is active and ongoing, along with our colleagues at NIH and VA, so that we can collaboratively assess in real-time what the right paths might be.

(Mark Paxton): Very good. Thank you. I know this is perhaps beyond the scope of this call, but at least with respect to how these swabs are used in specimen collection kits, would that answer be the same for any of the transport media with respect to sterility assurance? Over.

Dr. Brenner: Yes. Another great question. And transport media is a topic that comes up a lot on our in vitro diagnostic town hall calls. I don't have a specific response to that in the case of 3D printed swabs other than to say we are aware that all of the steps from collection of specimen to analysis of the sample by whatever instrumentation or assay is used could impact the quality of the results.

So we need to be very careful to investigate media and anything else that is in

that pathway regardless of whether the swab is 3D printed or a traditional swab. So it's an important piece of the puzzle in this case just like the other puzzles.

(Mark Paxton): Yes, ma'am. Thank you.

Coordinator: Our next question comes from (Buren). Your line is now open.

(Buren): Hi, there. Thank you very much for the opportunity here. So I represent several contract manufacturers and I wanted to get an idea. There is talk that, you know, we do have a shortage of these swabs. But does anybody know exactly in terms of what kind of quantities we're looking for in the short kind of long-term?

The reason of why I ask about the short and long-term is usually 3D printing is very good for a short-term production run with the 300,000, 400,000, a million and so forth. But if you're thinking about the long-term in, you know, six months, a year and so on and so forth, we may be able to deploy other technologies like injection molding to essentially produce components that are very similar.

So I just kind of wanted to get an idea about, you know, any sort of quantity requirements that anybody would know about right now in the short-term and in the long-term as well and then sort of the way that we may be looking at injection molding as well as 3D printing as well.

Dr. Brenner: This is Sara from FDA. An excellent question. And that's certainly a hot topic in discussions that we've participated in beyond the agency. I can't give you a firm number of what's needed. That type of information in current projections are sort of held higher up in the federal government with task forces such as

the ones run from the White House and FEMA on national supply chain strategy.

So I won't venture, you know, to give any numbers that might be incorrect as of today. But you're absolutely right in pointing out the differences in capacity for short versus long run. And injection molding and other techniques are ones that have been brought to our attention.

So I would pause on that question for now and I would encourage you to check-in or seek answers for those types of quantitative projection questions with sources like FEMA's task force on supply chain.

You can also shoot us an email and I could see if we could get an appropriate response for you that would not be attributed just to us and the experts on the phone today but across the federal government and what they're making publicly available on that.

I'd also like to ask if Matthew Di Prima has any comments or James Coburn, since both are technical experts in alternative manufacturing methods, if they have any additional comments on injection molding or the speed and capacity of production for these types of methods.

If you don't that's fine, but I wanted to pass it over in case you have a burning thought on the topic.

James Coburn: Hi. This is James. I'll just make one comment. I don't have a better number for the exact need and the time for that need. But one of the things that we have been looking at is not just the overall need for things like swabs, but the local need for those things as well with the transport issues or the shipping and movement issues from place to place.

Sometimes having a local source especially in this time where people are locked down can be very useful. And it also makes it even harder to engage optimal capacity or optimal need for any given locality.

But just when you're thinking about that, you can take that into account as well. It's not just the bulk overall need for the country. It's where every locality might need that piece of medical equipment.

(Buren): Excellent. Okay. Thank you.

Coordinator: Our next question comes from Al. Your line is now open.

Al Siblani: Hi. This is Al Siblani. I'm the CEO for EnvisionTEC. We're a manufacturer of 3D printing materials and we've been heavily involved with BIDMC to address the shortage of the NP swabs. Thank you all for taking the time today and primarily thanks to Sara who has been communicating with our staff on the NP swabs.

I have a couple questions. Just a little bit of background, you know, EnvisionTEC for the last 18 years have been delivering Class 1 devices. So this kind of falls in our lap and we're very comfortable in doing that.

Given what we have done so far where we have actually been granted testing on county-wide level, on city-wide level, like the City of New York where people are getting tested with our swab and as well we were even granted state-wide testing from some of the state governments.

My question is really kind of - it addresses the mechanical testing that you talked about. You mentioned tensile, flexional and torsional. And in our last

call with the FDA there was a mention that we should be getting some guidelines on that.

Do you have any type of timeline on this? Is this days or weeks? I mean, we are in a pandemic. There's a lot of need for these swabs and there is a significant shortage. And I want to add one thing which is very important before I pass it on to you is, you know, today our capacity is about 3 to 4 million swabs a month and we're scaling up to go to 10 million a month.

So this can definitely be a very good way to build supplies in the cloud using 3D printing. So can I get a sense of when those guidelines, specifically on the mechanical testing, will be provided to us.

Dr. Brenner: Yes. This is Sara from FDA. Thank you for everything that you're doing and everyone on the call is doing and on that question. We're very aware that folks are looking for this type of information. Unfortunately I can't give you an exact number of days today with regards to, you know, when that sort of information would come from FDA.

But what I can say is that in the conversation that has been ongoing here for the last hour and offline for many weeks now with our partners at NIH and VA, the community, which includes federal experts, has been putting together more specific information that folks, you and others, would want to take into consideration when you're performing different types of testing.

So the most immediate answer I can provide right now is to check back to the link that NIH is posting and the information that NIH will be providing on their site while we, the royal we, which includes FDA, continues to work on what we'll be able to communicate to the public.

I would encourage you though to continue to reach back. So feel free to email me directly by the middle of next week if you don't feel like sufficient information has been provided and is acceptable to you. My email is Sara.Brenner@fda.hhs.gov.

Al Siblani: Great. Thank you for that. I appreciate it. Thank you all.

Coordinator: And that will be our last question for the presentation. I'd like to turn the call back over to Irene.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH webpage at [www.fda.gov/training/cdrhlearn](http://www.fda.gov/training/cdrhlearn) by Friday, May 22.

If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback.

Following the conclusion of today's town hall, please complete a short 13 question survey about your FDA CDRH town hall experience. The survey can be found at [www.fda.gov/cdrhwebinar](http://www.fda.gov/cdrhwebinar) immediately following the conclusion of today's live discussion. Again, thank you for participating. This concludes today's town hall.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time. Speakers, please allow a moment of silence and stand by for your post-conference.

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